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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,010	CLAROT ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,31 and 40-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,31 and 40-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 30-31 and 40-57 are pending. Applicant previously cancelled claim 12. Applicants have newly cancelled claims 1-11, 13-29, and 32-39. Claims 41-57 are new. Receipt and consideration of Applicants' claim amendments and remarks/arguments, submitted on December 11, 2007 are acknowledged. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments.

Moot Rejections/objections

All rejections and/or objections of claim(s) 1-11, 13-29, and 32-39 cited in the previous office action mailed on October 16, 2007 **are moot**, because said claim(s) have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 40 recites "extracts thereof" in reference to camphor, eucalyptus oil, menthol, and azulen; however, Applicants'' specification only supports extracts of natural oils (see paragraph [0029] in Applicants' specification). Thus, extracts of camphor, menthol, and azulen lack adequate written support.

Claims 47-48 recite hydroxyethyl cellulose as a thickener. Applicants' specification does not identify hydroxyethyl cellulose as being a thickener (see original claim 1 or paragraph [0033[). Thus, the inclusion of hydroxyethyl cellulose in a group consisting of possible thickeners according to Applicants' disclosure lacks adequate written support.

The remaining claims are rejected as depending from a rejected claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-31 and 40-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 40 recite that the compositions are intended to reduce symptoms "associated with allergies and the common cold". The specification does not define or set forth what degree of association is required for a particular symptom to be considered "associated with allergies and the common cold." Thus, an ordinary skilled artisan would be unable to ascertain the metes and bounds of the phrase "symptoms associated with allergies and the common cold." Appropriate correction and clarification are required.

Claim 30-31 are vague and indefinite, because the active ingredient is described as comprising. The term "active ingredient" implies a singular molecular entity. Description of a molecule (i.e. active ingredient) as comprising "oxymetazoline hydrochloride" implies that oxymetazoline hydrochloride forms only part of the chemical structure of the required active ingredient. Thus, an ordinary skilled artisan would be unable to ascertain unambiguously what the required active ingredient was.

The remaining claims are rejected as depending from a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269) and Hensley et al. (U.S. Patent No. 6,673,835).

Applicant Claims

Applicants claim a composition for application to a nasal membrane to reduce symptoms associated with allergies and the common cold comprising (i) about 90-99.999 % w/w carrier, (ii) about 0.001 to about 5.0 $ w/w oxymetazoline hydrochloride, (iii) about 0.00001 to about 5.0 % w/w of a permeation enhancer comprising liposomes, wherein the composition has a viscosity between about 2,500 to about 40,000 centipoise.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Davidson teaches a composition for reducing the duration of a common cold comprising: about **90 to about 99.1 weight percent of a carrier**; **about 0.9 to about 2.0 weight percent zinc gluconate**, wherein said composition has a **viscosity greater than about 5,000 centipoise**, wherein the carrier includes **glycerin** in an amount of about **0.05 to about 3.0 weight percent,** further comprising a thickener selected from the group consisting of: **carbohydrate thickeners, carrageenan, sugar, guar gum, and methylcellulose**, and further comprising about **0.01 to about 0.10 weight percent methanol** (claims 9-14). Davidson teaches that **zinc in the nasal cavity acts as a decongestant**, enhancing the discharge of mucous and inhibiting the generation of new mucous. **Menthol is also a decongestant** and a bronchial dilator (column 6, lines 1-8). Haslwanter teaches that an over-the-counter (OTC) product under the trade name AFRIN® comprises a composition containing vapors of **menthol**, **eucalyptol** and **camphor, oxymetazoline hydrochloride,** and an aqueous carrier containing **benzalkonium chloride**, **glycerine**, phenylmercuric acetate, sorbitol, polysorbate 80 is currently available (column 1, lines 37-44).

Haslwanter teaches nasal compositions comprising **oxymetazoline or a pharmaceutically acceptable salt thereof** in the range of about **0.01 % to about 0.1 % by weight/volume (w/v)**, **benzyl alcohol (a preservative)** in an amount from about **0.10 to 5.00 % w/v**, a surfactant (i.e. emulsifier) from about 0 to 2.00 % w/v, **disodium EDTA** from about 0 to 0.1 % w/v, **benzalkonium chloride** from about 0.01 % to 0.3 % w/v, and pharmaceutically acceptable **buffers**, including **phosphate**. In Example 2, Haslwanter teaches several specific surfactants, including a **fatty acid ester of polyethylene glycol, and specific buffers (sodium phosphate monobasic and sodium phosphate dibasic)** (i.e. Polysorbate 80) (column 2, lines 40-45, 56-60, 65-67; column 3, lines 1, 13-15, 23-27, 28-33; and Example 2). Examples 3-5 teach similar compositions too.

Hensley teaches nasal zinc gel compositions comprising carrier, thickeners, **permeation enhancers, such as liposomes**, etc. (title; abstract; col. 8, lines 56-64), wherein said compositions have a **viscosity in the range of 2,500 to 40,000 centipoise**.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Davidson lacks the teaching of decongestant compositions comprising permeation enhancers, preservatives, emulsifiers, and buffers. This deficiency is cured by the teachings of Haslwanter. Davidson lacks the teaching of liposomes. This deficiency is cured by the teachings of Hensley.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person or ordinary skill in the art at the time of the instant invention to combine the teachings of Davidson, Haslwanter, and Hensley, because all references are in the same field of endeavor, namely nasal compositions comprising known decongestants (e.g. zinc, menthol, oxymetazoline hydrochloride, etc.). Furthermore, it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Davidson and Haslwanter, because it is obvious to combine known decongestants per the teaching of Davidson, and a commercially available OTC decongestant at the time of the instant invention was known to comprise a mixture of decongestants, water, an emulsifier, and a preservative. An ordinary skilled artisan would also have looked to the teachings of Haslwanter and Hensley to ascertain what excipients and excipient amounts were found suitable in similar nasal compositions. A person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of successfully incorporating liposomes as permeation enhancers, because liposomes are art-recognized permeation enhancers (Hensley). The ordinary skilled artisan would have had a reasonable expectation of combining the teachings of Davidson, Haslwanter, and Hensley because all references teach similar nasal compositions comprising known decongestants, and the combination of different decongestants would have been reasonably expected to exhibit at least an additive decongestant effect. Regarding the formulation viscosity, an ordinary skilled artisan in optimizing the amount of thickener would necessarily optimize the composition's viscosity. It is also noted that the viscosity range taught by Hensley is the same range taught in Applicants' claim 30. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the

invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-31, 40-48, and 52-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-10 and 33 of U.S. Patent No. 7,115,275 (USPN '275). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant application and USPN '275 are overlapping in scope and mutually obvious. Independent claim 30 of the instant application claims a composition for application to a nasal membrane comprising (i) about 90-99.999 % w/w carrier, (ii) about 0.001 to about 5.0 $ w/w oxymetazoline hydrochloride, (iii) about 0.00001 to about 5.0 % w/w of a

permeation enhancer comprising liposomes, wherein the composition has a viscosity between about 2,500 to about 40,000 centipoise. Independent claim 1 of USPN '275 claims a system for delivering a composition to a nasal membrane comprising (a) an applicator assembly and (b) a composition having a viscosity greater than about 1,500 centipoise. Dependent claim 2 of USPN '275 indicates that the composition comprises one or more active agents including a decongestant. Dependent claim 3 of USPN '275 indicates that suitable decongestants include oxymetazoline hydrochloride, camphor, eucalyptus oil, menthol, and azulen, etc. Dependent claim 4 indicates that the system further comprises at least one of a carrier, thickener, permeation enhancer, preservative, an emulsifier, and a buffer. Suitable thickeners are set forth in claim 5 of USPN '275. Suitable permeation enhancers are claimed in claim 6 of USPN '275 and include liposomes. Suitable emulsifiers and buffers are set forth in dependent claims 9 and 10, respectively, of USPN '275. The difference between the claims of the instant application and USPN '275 is that the claims of USPN '275 do not specify the amount of carrier, oxymetazoline hydrochloride active, permeation enhancer, preservative, aromatic substance (e.g. camphor), etc. No specific ranges are expressly recited in the claims of USPN '275, thus all ranges are contemplated. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been

obvious at the time of applicant's invention. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 30-31, 40-48, and 52-57 *prima facie* obvious over claims 2-10 and 33 of U.S. Patent No. 7,115,275 (USPN '275)

Other Matter

It appears that the word "into" has been misspelled as "in" in claim 57, line 4. Applicants are respectfully requested to correct the typographical error.

Conclusion

Claims 1-11 and 13-29, and 32-39 are rejected. Claims 30-31 and 40 are objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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